

**SOP Title:** Periodic / Biennial Review of SOPs

**SOP Number:** 21917

**Revision:** 01

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#### 1. PURPOSE

The purpose of this procedure is to define the process for biennial review of SOPs.

#### 2. SCOPE

This procedure applies to SOPs and forms managed in the Electronic Documentation System (eDMS) (MasterControl).

#### 3. RESPONSIBILITIES

##### 3.1 The Head of Document Control

- Defines the procedure.

##### 3.2 Biopharmaceutical Quality Assurance Document Control (BQAD).

- Tracks and trends the completion of changes.

##### 3.3 Owners and Authors

- Reviews the documents for accuracy.
- Reviews the Notes section of the infocard for requested changes on the next revision.
- Updates documents for changes.
- Completes reviews in a timely fashion.

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### 4. PROCEDURE

#### 4.1 Frequency

- 4.1.1 The eDMS launches a review task 60 days prior to the next review date identified on the document Infocard.
- 4.1.2 Everyone in the task must complete the review within 60 days.
- 4.1.3 Modifications to the route to add or remove users can only be done by the System Administrator.

#### 4.2 Document Accuracy

- 4.2.1 The owner and author review the document for accuracy. Examples of items to review includes but is not limited to:
  - Part Numbers
  - References
  - Reagents
  - Steps
  - Reporting
  - Process changes
- 4.2.2 In the event changes are required, any associated forms are evaluated by the owner and author for related changes, and included in the same task packet.

#### 4.3 Review

- 4.3.1 The task indicates "Review" and includes the document number and all or part of the title.
- 4.3.2 Choose the task.

#### Task Details: Review: 26200-TEST 00 Packet Demo

##### Instructions

Please review the attached InfoCard(s) for accuracy, if changes are required please sign off task as "NEEDS UPDATE" and include change description in comments. If NO changes are required and InfoCard is accurate please sign off the task as "REVIEWED".

DOCUMENT NUMBER	TITLE	FILE NAME	ACTIONS
26200-TEST	Packet Demo	TEST SOP1.docx	  

Cancel

Continue

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4.3.3 Review the document. By choosing the file under [ACTIONS]. Choose [Continue].

4.3.4 Determine the Status

- **Reviewed** – The document does not require update.

If no updates are required, all reviewers are required to determine the same status.

- **Needs Update** – The document requires update.

If updates are required, you are required to include comments of what needs updated. Be as specific as possible.

4.3.5 Apply your electronic signature.

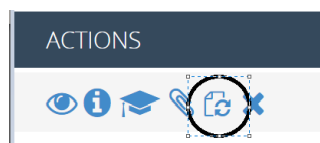
4.4 Needs Update

4.4.1 After any reviewer determines that an update is needed, a draft is created by the system and a revision task is sent to the author, owner and BQAD. This is a one-step collaboration where changes can be made prior to launching the document for review.

4.4.2 The draft infocard is now in a one-step collaborate route, in your tasks. Use the icon to make changes. Use the Track Changes function in Microsoft Word or Comments functionality to show the changes being made. Save your changes.

**NOTE:** If the document is a .doc rather than a .docx you will need to save it on your desktop as .docx and upload the file. The automatic integration of Microsoft works with .docx, .xlsx document file types.

4.4.3 Update the infocard main file by selecting the [Update Infocard Main File] under [Actions].



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- 4.4.4 End the collaboration by selecting [Signoff]. Enter your electronic signature and [Save]. A message to start a new packet will display. Choose [Yes] to create a new packet and launch a task.

**Sign Off on Collaboration: Revision:**  
**ZPQ TEST - 0001 01**

The Collaboration step is complete. Do you want to send these InfoCard(s) on a new packet?

- 4.5 Refer to SOP 21010 User Manual for MasterControl Documents. For instructions on creating the Task Packet and sending the document for review and approval.
- 4.6 Changes requested prior to the biennial review that are not immediately required or required on next update are noted in the notes section of the Infocard. The author, owner should review the infocard and make the requested changes.

### 5. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21010	User Manual for MasterControl Documents